

REMARKS

I. Status of the Application

Claims 24, 27, 28, 30-47, 49-59, and 60-62 are currently pending in the present application. Claims 1-23, 25, 26, 29, and 48 have been cancelled. Claims 49-59 have been withdrawn as non-elected groups pursuant to a restriction requirement. Claims 60 and 61 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 24, 28, 30-32, 37-43, 45, 48, and 60-62 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Coudray et al. (*Br. J. Nutrition*, 1998; hereinafter “Coudray”), with evidence provided by Kleemann et al. (US 5,906,852, hereinafter “Kleemann”). Claims 24, 28, 30-32, 37-45, 47, and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Coudray in view of Kleemann. Claims 24, 27, 28, 30-47, and 60-62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Xu (US 6,083,921), Squires (WO 98/11778), Carenzi et al. (US 5,080,906; hereinafter “Carenzi”), and the admitted state of the art.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants’ novel invention. Specifically, independent claims 24 and 60 have been amended to recite a liquid food product or drink. Support for this amendment can be found throughout the specification as filed, for example from page 16, line 24 to page 17, line 3. Claims 24 and 60 have also been amended to recite polysaccharides that induce interferon production which are isolated from the recited sources. Support for this amendment can be found throughout the application as filed, for example from page 10, line 10 to page 11, line 14. Claims 24 and 60 have also been amended to delete the term fungi. Claim 47 has been amended to refer to the liquid food product or drink of claim 24, and to delete the terms capsule, tablet, lozenge, powder, agglomerate, paste, liquid, bar, drink, pudding, ice cream, and sauce. Claims 60 and 61 have

been amended to delete the daily dose elements and instead recite 1-200 mg zinc and 0.5-500 mg chlorogenic acid and/or functional analogs thereof, and 50-2000 mg N-acetylcysteine and 2-300 mg chlorogenic acid and/or functional analogs thereof, respectively. Support for these amendments can be found throughout the specification as filed, for example in Table 1 and at page 15, lines 5-12.

No new matter has been added. Applicants respectfully request entry of the foregoing amendments and reconsideration of the present application in view of the following remarks, which are intended to place this application in condition for allowance.

II. Claims 60 and 61 Are Definite

At page 2, paragraph 3 of the instant Office Action, claims 60 and 61 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner is of the opinion that defining the claimed food product or drink in terms of daily dosage amounts is unclear. Applicants respectfully traverse the rejection. Nevertheless, Applicants have amended claims 60 and 61 to delete the daily dosage language and instead define the claimed food product or drink as having the recited amounts of zinc, chlorogenic acid and/or functional analogs thereof, and N-acetylcysteine. Thus, the subject claims are definite. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejection and allowance of claims 60 and 61.

III. Claims 24, 28, 30-32, 37-43, 45, and 60-62 Are Novel over Coudray

At page 3, second paragraph of the instant Office Action, claims 24, 28, 30-32, 37-43, 45, 48, and 60-62 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Coudray.

Applicants respectfully traverse the rejection. Claim 48 has been cancelled, so the rejection against it is moot.

The Examiner is of the opinion that the cellulose disclosed by Coudray reads upon the recited polysaccharides from the recited sources. The Examiner refers to Kleemann for teaching that cellulose is a polysaccharide composed of 1,4-linked glucose units which is a ubiquitous fiber found in all plant sources including fungi. However, contrary to the Examiner's opinion, the properties of cellulose may vary dependent upon the source from which it originates. In particular as taught by e.g. <http://www.cem.msu.edu/%7Ereusch/VirtualText/carbhyd.htm#carb1>, section "8. Polysaccharides" (and included herein as Attachment A): "As a polymer of glucose, cellulose has the formula $(C_6H_{10}O_5)_n$ where n ranges from 500 to 5,000, depending on the source of the polymer." So, cellulose from different sources may at least be distinguished by different numbers of glucose units and thus different molecular weights. Kleemann even specifically teaches that there are various sources of cellulose (and thus different types of cellulose). Accordingly, the term "cellulose" is a genus, of which "cellulose from fungus," "cellulose from bacteria," "cellulose from oak," etc. are all species which may be different from one another, particularly in terms of chain length and molecular weight. One of ordinary skill in the art would understand that differences in the chain length and molecular weight of a polymer significantly affect the properties of that polymer, such as, for example, biological activity in addition to physical properties such as strength, viscosity, melting point, degree of crystallinity, etc. Accordingly, the source of cellulose can be used as a distinguishing feature.

Moreover, the cellulose disclosed by Coudray is not inherently a polysaccharide which has the property of inducing interferon production, as recited by amended independent claims 24 and 60. Cellulose is a water-insoluble fiber which is not digested by humans, because humans

do not have cellulose-digesting bacteria in the digestive tract, as taught by e.g. <http://www.talkorigins.org/faqs/vestiges/appendix.html>, section title “The caecum: a specialized herbivorous organ.” (and included herein as Attachment B). Klemann agrees, disclosing that cellulose is negligibly digestible, so it would make a good low-calorie replacement for starch in food products (column 1, lines 25-29). Since cellulose is not broken down in the human digestive tract, it is not absorbed by the bloodstream, and thus cannot act to induce interferon production in the body. In contrast, the recited β -1,3-glucans, arabinogalactans, and polysaccharides that induce interferon production which are isolated from the recited sources, are water-soluble fibers. The American Association of Cereal Chemists defines soluble fiber as: “the edible parts of plants or similar carbohydrates resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine.” The recited soluble fibers can be fermented by bacteria in the human large intestine. The fermentation products of these soluble fibers, e.g. short-chain fatty acids, can then be absorbed by the large intestine into the bloodstream and act to induce interferon production, and consequently to stimulate or enhance the immune system. Cellulose, which is not fermented in and absorbed by the human large intestine, is not operative to induce interferon production. Therefore, the polysaccharides recited in claims 24 and 60 do not read on cellulose. Hence, Coudray fails to teach or suggest a polysaccharide that induces interferon production which is isolated from the recited sources. Nevertheless, Applicants have removed fungi from the group of sources for polysaccharides recited in claims 24 and 60 to streamline the examination procedure.

The Examiner is also of the opinion that the semi-liquid food as disclosed by Coudray reads upon a solution, liquid, gel, and/or suspension. Applicants respectfully disagree. The specification as filed from page 16, line 30 to page 17, line 3 discloses that a preparation

according to the invention may be a liquid or a semi-liquid shaped product. Thus Applicants draw a distinction between liquid and semi-liquid: liquids are fluid but semi-liquids are able to hold a shape at least for a short period of time. Applicants have amended independent claims 24 and 60 to recite liquid food products or drinks. Applicants have also amended dependent claim 47 to recite a solution, an emulsion, a suspension, a lemonade, a fruit juice, or a dairy drink, all of which are liquid, not semi-liquid, forms of food product or drink. Thus the recited liquid food product or drink does not read upon the semi-liquid food of Coudray.

For at least the foregoing reasons, Coudray fails to teach or suggest each and every limitation of independent claims 24 and 60, and their respective dependent claims. For at least the forgoing reasons, the subject claims are novel over Coudray. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claims 24, 28, 30-32, 37-43, 45, and 60-62.

IV. Claims 24, 28, 30-32, 37-45, and 47 Are Patentable over Coudray in View of Kleemann

At page 4, third paragraph of the instant Office Action, claims 24, 28, 30-32, 37-45, 47, and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Coudray in view of Kleemann. Applicants respectfully traverse the rejection. Claim 48 has been cancelled, so the rejection against it is moot.

The Examiner is of the opinion that the claimed invention is rendered obvious by the combination of Kleemann's teaching of cellulose from fungi with Coudray's food meal preparation. Applicants respectfully disagree. As discussed above in section III, cellulose from different sources can be distinguished at least by different chain length and molecular weight, so not all cellulose is the same or has the same properties. In particular, as discussed above,

cellulose does not have the property of being a polysaccharide that induces interferon production, as recited in claim 24. Furthermore, Klemann does not suggest the use of cellulose or any other polysaccharide from fungus or another plant source in a preparation for stimulating or enhancing an immune system. The skilled artisan, knowing that cellulose is not digested and absorbed in humans, would not be motivated to add cellulose to a preparation for stimulating or enhancing the immune system. Nevertheless, Applicants have removed fungi from the group of sources for polysaccharides recited in claim 24 to streamline the examination procedure.

Coudray also fails to provide teaching, suggestion or motivation for a preparation for stimulating or enhancing an immune system, and certainly not such a preparation including zinc, chlorogenic acid or functional analogs thereof, and at least one polysaccharide selected from the group consisting of β -1,3-glucans, arabinogalactans, and polysaccharides that induce interferon production which are isolated from the sources recited in claim 24. Coudray is completely silent on the immunological effects of zinc, chlorogenic acids and functional analogs, or any other ingredient in its disclosed rat food. Coudray teaches away from combining zinc with chlorogenic acid, disclosing that zinc absorption in rats fed on chlorogenic acid was significantly less than in the control group (see abstract). Coudray teaches that polyphenols, such as chlorogenic acid, may chelate the zinc ions to prevent absorption of zinc (see page 575, right-hand column to page 576, left-hand column, first paragraph). Thus, the skilled artisan reading Coudray would not be motivated to combine chlorogenic acid with zinc as nutrients in a food product or drink, much less in a preparation wherein both zinc and chlorogenic acid are used to stimulate T-lymphocytes (specification page 9, line 20 to page 10, line 13), and thus to stimulate or enhance an immune system. In contrast, Applicants have found no indications that the bioavailability of zinc or chlorogenic acid is a problem in preparations according to the claimed

invention. These active ingredients in the preparation are absorbed by the body and beneficially stimulate the immune system.

Klemann fails to remedy the deficiencies of Coudray. Klemann is completely silent on T-lymphocyte, interferon, or immune system stimulation, and is also silent on the combination of chlorogenic acid and zinc. So Klemann combined with Coudray fail to teach or suggest a polysaccharide that induces interferon production which is isolated from the recited sources, and also fail to provide motivation to combine zinc with chlorogenic acid and said polysaccharide in a liquid food product or drink as a preparation for stimulating or enhancing the immune system.

Therefore, Coudray and Klemann fail to teach or suggest each and every claim limitation, and also fail to provide motivation to combine or modify their teachings to arrive at the claimed invention. For at least the foregoing reasons, claim 24 and its dependent claims are not obvious over Coudray in view of Klemann. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 24, 28, 30-32, 37-45, and 47.

V. **Claims 24, 27, 28, 30-47, and 60-62 Are Patentable over Xu, Squires, Carenzi, and the Admitted State of the Art**

At page 5, third paragraph of the instant Office Action, claims 24, 27, 28, 30-47, and 60-62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Xu, Squires, Carenzi, and the admitted state of the art. The Examiner is of the opinion that the combination of Xu's pharmaceutical composition comprising chlorogenic acid and zinc stearate in the form of a tablet, Squires' medical composition comprising a functional analog of chlorogenic acid and polysaccharides such as arabinogalactans, and Carenzi's N-acetylcysteine composition render the subject claims obvious. Applicants respectfully traverse the rejection.

Applicants maintain and incorporate herein by reference the reasons for non-obviousness discussed in section X of the previous Office Action response filed on November 2, 2006. In addition, independent claims 24 and 60 have been amended to recite a liquid food product or drink. A tablet is not a **liquid** food product or drink. The skilled artisan would have no motivation to include zinc in the liquid food product or drink as recited, because Xu only mentions zinc in the form of zinc stearate as one of a long list of excipients (inactive or inert ingredients) for **solid** tablet formulations. The skilled artisan would have no expectation that an excipient for solid tablets could be successfully used in liquid formulations. In fact, zinc stearate is not water soluble and therefore is not suitable for use in an aqueous liquid food product or drink. Furthermore, zinc stearate is not suitable for consumption in a true food product or drink because of its soapy taste. The skilled artisan would have no motivation to use the excipient zinc stearate as an active ingredient in an effective amount to be capable of inducing the production of interferon-gamma *in vivo*, in combination with chlorogenic acid (or a functional analog thereof) and the specific polysaccharides as recited in the liquid food products or 'drinks of claims 24 and 60. Nor would the skilled artisan be motivated to modify zinc stearate to another zinc salt, because Xu does not suggest the use of zinc in liquid formulations, and certainly not in liquid food products or drinks.

Since Squires and Carenzi are silent on the inclusion of zinc, the combination of Xu, Squires, and Carenzi fails to teach, suggest, or provide motivation for a liquid food product or drink comprising zinc, chlorogenic acid or a functional analog thereof, and the recited polysaccharides. In fact, Xu, Squires, and Carenzi do not even disclose a food product or drink. All three are directed to pharmaceutical/medical compositions. Applicants make a distinction between pharmaceuticals and food products (specification page 16, line 11 to page 17, line 15).

Webster's Ninth New Collegiate Dictionary defines pharmaceutical as "a medicinal drug." The same dictionary defines drug as "**a substance other than food** intended to affect the structure or function of the body."

Therefore, Xu, Squires and Carnezi fail to teach or suggest each and every claim limitation, and also fail to provide motivation to combine or modify their teachings to arrive at the claimed invention. For at least the foregoing reasons, independent claims 24 and 60 and their dependent claims are not obvious over Xu in view of Squires, Carenzi, and the state of the art. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 24, 27, 28, 30-47, and 60-62.

VI. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of claims 24, 27, 28, 30-47 and 60-62. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below. The Commissioner is hereby authorized to apply any additional charges or credits for overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: April 12, 2007

for

Jane P. White, Reg. No. 57,531

John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
(617) 720-9600